## Amendments to the Claims

1. (original) The use of pimecrolinus in the manufacture of a medicament for the treatment of inflammatory disease in a selected patient population, wherein the patient population is selected on the basis of the genotype of the patients at a genetic locus from the TNF gene cluster indicative of efficacy of pimecrolimus in treating inflammatory disease.

2. (original) The use of tacrolimus in the manufacture of a medicament for the treatment of inflammatory disease in a selected patient population, wherein the patient population is selected on the basis of the genotype of the patients at the *CCR2* genetic locus indicative of efficacy of tacrolimus in treating inflammatory disease.

3. (original) A method for treating a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus or tacrolimus is indicated, comprising the steps of:
   (a) obtaining the genotype of a subject at a genetic locus from the TNF gene cluster indicative of efficacy of a selected macrolactam formulation in treating the condition;
   (b) administering either the selected macrolactam formulation or an alternative treatment for the condition to the subject.

4. (original) The method of claim 3, wherein the selected macrolactam formulation comprises pimecrolimus.

5. (original) The method of claim 3, wherein the selected macrolactam formulation comprises tacrolimus.

6. (currently amended) The method of ~~any one of claims 3 to 5~~ claim 3, wherein the genetic locus is the human *TNF* gene or a gene in a vertebrate species homologous to the human *TNF* gene.

7. (currently amended) The ~~use of claim 1 or the~~ method of ~~any one of claims 3 to 6~~ claim 3, wherein the genetic locus is the (-1031) *TNF* locus of the human *TNF* gene or a corresponding locus in a vertebrate species homologous to the human *TNF* gene.

8. (currently amended) The method of ~~any one of claims 3, 4, 6 or 7~~ claim 3, wherein the selected macrolactam formulation comprises pimecrolimus, when the (-1031) *TNF* genetic locus has a TT genotype.

9. (currently amended) The method of ~~any one of claims 3 to 7~~ claim 3, wherein the alternative treatment for the condition is selected from the group consisting of a high dose of pimecrolimus, pimecrolimus and an alternative immunosuppressant, and an alternative immunosuppressant, when the (-1031) *TNF* locus has a CC or CT genotype.

10. (original) The method of claim 9, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, tacrolimus and sirolimus.

11. (original) The ~~use of claim 1 or the~~ method of claim 3, wherein the genetic locus is the human *LTA* gene or a gene in a vertebrate species homologous to the human *LTA* gene.

12. (currently amended) The ~~use of claim 1 or 11 or the~~ method of claim 3 ~~or 11~~, wherein the genetic locus is the ASN60THR *LTA* locus of the human *LTA* gene or a corresponding locus in a vertebrate species homologous to the human *LTA* gene.

13. (currently amended) The method of ~~any one of claims 3, 11 or 12~~ claim 3, wherein the selected macrolactam formulation comprises pimecrolimus, when the ASN60THR *LTA* genetic locus has an AA or AC genotype.

14. (currently amended) The method of ~~any one of claims 3, 11 or 12~~ claim 3, wherein the alternative treatment for the condition is selected from the group consisting of a high dose of pimecrolimus, pimecrolimus and an alternative immunosuppressant, and an alternative immunosuppressant, when the ASN60THR *LTA* locus has a CC genotype.

15. (original) The method of claim 14, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, tacrolimus and sirolimus.

16. (original) A method for treating a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus or tacrolimus is indicated, comprising the steps of:

(a) obtaining the genotype of a subject at a genetic locus indicative of efficacy of a selected macrolactam formulation in treating the condition, where the genetic locus is the human *CCR2* gene or a gene in a vertebrate species homologous to the human *CCR2* gene;

(b) administering either the selected macrolactam formulation or an alternative treatment for the condition to the subject.

17. (currently amended) The ~~use of claim 2 or the~~ method of claim 16, wherein the genetic locus is the VAL64ILE *CCR2* locus of the human *CCR2* gene or a corresponding locus in a vertebrate species homologous to the human *CCR2* gene.

18. (currently amended) The method of claim 16 ~~or 17~~, wherein the selected macrolactam formulation comprises tacrolimus, when the VAL64ILE *CCR2* genetic locus has a GG genotype.

19. (currently amended) The method of claim 16 ~~or 17~~, wherein the alternative treatment for the condition is selected from the group consisting of a high dose of tacrolimus, tacrolimus and an alternative immunosuppressant, and an alternative immunosuppressant, when the VAL64ILE *CCR2* locus has an AG genotype.

20. (currently amended) The method of claim 16~~, 17 or 19~~, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, pimecrolimus and sirolimus.

21. (original) A method for treating a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus is indicated, comprising the steps of:

(a) obtaining a measurement of the level of TNF-α mRNA in a sample from a subject, where the sample is taken from non-inflamed tissue; and

(b) either:

(i) administering a pimecrolimus formulation to the subject when the level of TNF-α mRNA in the sample is low or normal; or

(ii) administering either (A) a pimecrolimus formulation in combination with another immunosuppressant or (B) another immunosuppressant to the subject when the level of TNF-α mRNA in the sample is elevated.

22. (original) A method for treating a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus is indicated, comprising the steps of:

(a) obtaining a measurement of the level of TNF-α protein in a sample from a subject, where the sample is taken from non-inflamed tissue; and

(b) either:

(i) administering a pimecrolimus formulation to the subject when the level of TNF-α protein in the sample is low or normal; or

(ii) administering either (A) a pimecrolimus formulation in combination with another immunosuppressant or (B) another immunosuppressant to the subject when the level of TNF-α protein in the sample is elevated.

23. (original) A method for determining a treatment strategy for a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus is indicated, said method comprises analyzing the level of TNF-α mRNA or TNF-α protein in a sample from the subject; and wherein the treatment strategy comprises the selection of a pimecrolimus formulation as treatment when the level of TNF-α mRNA or TNF-α protein in the sample is low or normal; or the selection of either (A) a pimecrolimus formulation in combination; with another immunosuppressant or (B) another immunosuppressant as treatment when the level of TNF-α mRNA or TNF-α protein in the sample is elevated.

24. (cancelled) A method for choosing subjects for inclusion in a clinical trial for determining the efficacy of a pimecrolimus formulation, comprising the steps of:

(a) interrogating the genotype of a subject at the (-1031) TNF polymorphism locus;

(b) then:

(i) including in the trial if they are TT at this locus;

(ii) excluded if they are CC or CT at this locus; or

(iii) both (i) and (ii).

25. (cancelled) A kit for use in determining a treatment strategy for a condition, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus or tacrolimus is indicated, comprising:

(a) a reagent for detecting a biomarker of efficacy of treatment of the condition by a macrolactam formulation;

(b) a container for the reagent; and

(c) a written product on or in the container describing the use of the biomarker in determining a treatment strategy for the condition.

26. (cancelled) The kit of claim 25, wherein the biomarker is a genetic polymorphism in a gene selected from the group consisting of *TNF*, *LTA* and *CCR2*.

27. (cancelled) The kit of claim 25 or 26, wherein the reagent for detecting the biomarker is a set of primer pairs that hybridize to a polynucleotide on either the side of the genetic polymorphism in the gene selected from the group consisting of *TNF*, *LTA* and *CCR2* and which define a nucleotide region that spans the genetic polymorphism.

28. (cancelled) The kit of claim 25, wherein the biomarker is the level of TNF-α mRNA in a sample from a subject to be treated.

29. (cancelled) The kit of claim 25, wherein the biomarker is the level of TNF-α protein in a sample from a subject to be treated.

30. (original) A method for determining a treatment strategy for a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus or tacrolimus is indicated, said method comprises analyzing the genotype of a subject at a genetic locus from the TNF gene cluster indicative of efficacy of a selected macrolactam formulation in treating the condition.

31. (original) The method of claim 30, wherein the genetic locus is the human *TNF* gene or a gene in a vertebrate species homologous to the human *TNF* gene.

32. (currently amended) The method of claim 30 ~~or 31~~, wherein the genetic locus is the (-1031) *TNF* locus of the human *TNF* gene or a corresponding locus in a vertebrate species homologous to the human *TNF* gene.

33. (currently amended) The method of ~~any one of claims 30 to 32~~ claim 30, wherein the treatment strategy comprises the selection of a macrolactam formulation comprising pimecrolimus as treatment, when the (-1031) *TNF* genetic locus has a TT genotype.

34. (currently amended) The method of ~~any one of claims 30 to 32~~ claim 30, wherein the treatment strategy comprises the selection of a high dose of pimecrolimus, pimecrolimus and an alternative immunosuppressant, or an alternative immunosuppressant as treatment, when the (-1031) *TNF* locus has a CC or CT genotype.

35. (original) The method of claim 34, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, tacrolimus and sirolimus.

36. (original) The method of claim 30, wherein the genetic locus is the human *LTA* gene or a gene in a vertebrate species homologous to the human *LTA* gene.

37. (original) The method of claim 36, wherein the genetic locus is the ASN60THR *LTA* locus of the human *LTA* gene or a corresponding locus in a vertebrate species homologous to the human *LTA* gene.

38. (currently amended) The method of claim 36 ~~or 37~~, wherein the treatment strategy comprises the selection of a macrolactam formulation comprising pimecrolimus as treatment, when the ASN60THR *LTA* genetic locus has an AA or AC genotype.

39. (currently amended) The method of claim 36 ~~or 37~~, wherein the treatment strategy comprises the selection of a high dose of pimecrolimus, pimecrolimus and an alternative immunosuppressant, or an alternative immunosuppressant as treatment, when the ASN60THR *LTA* locus has a CC genotype.

40. (original) The method of claim 39, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, tacrolimus and sirolimus.

41. (original) A method for determining a treatment strategy for a condition in a subject, wherein the condition is selected from the group consisting of atopic dermatitis, psoriasis, asthma, inflammatory bowel disease, rheumatoid arthritis or other condition for which pimecrolimus or tacrolimus is indicated, said method comprises analyzing the genotype of a subject at a genetic locus indicative of efficacy of a selected macrolactam formulation in treating the condition, where the genetic locus is the human *CCR2* gene or a gene in a vertebrate species homologous to the human *CCR2* gene.

42. (original) The method of claim 41, wherein the genetic locus is the VAL64ILE *CCR2* locus of the human *CCR2* gene or a corresponding locus in a vertebrate species homologous to the human *CCR2* gene.

43. (currently amended) The method of claim 41 ~~or 42~~, wherein the treatment strategy comprises the selection of a macrolactam formulation comprising tacrolimus as treatment, when the VAL64ILE *CCR2* genetic locus has a GG genotype.

44. (currently amended) The method of claim 41 ~~or 42~~, comprising the selection of a high dose of tacrolimus, tacrolimus and an alternative immunosuppressant, or an alternative immunosuppressant as treatment, when the VAL64ILE *CCR2* locus has an AG genotype.

45. (original) The method of claim 44, wherein the alternative immunosuppressant is selected from the group consisting of hydrocortisone, cyclosporine, pimecrolimus and sirolimus.